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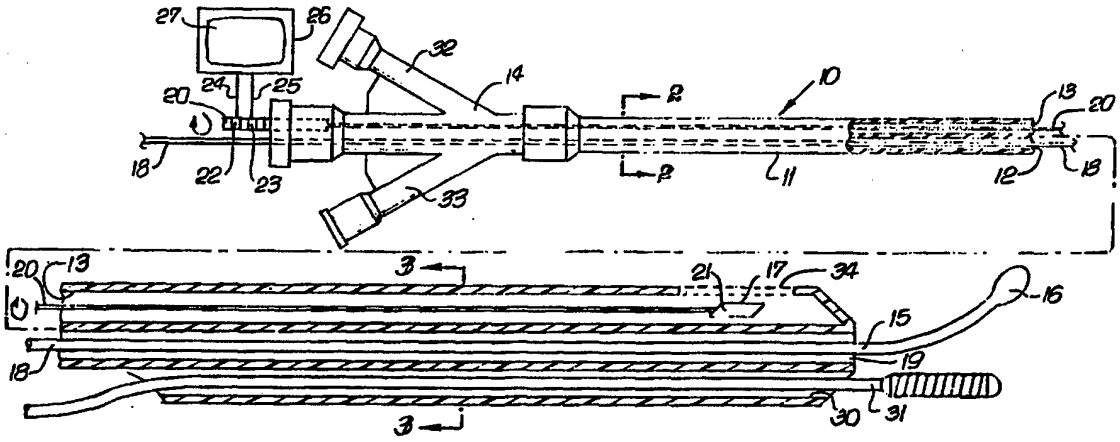

(57) Abstract

An intraluminal catheter (10) for the ultrasonic ablation of stenoses or occlusions in a body lumen such as peripheral or coronary arteries. The catheter has an elongated ultrasonic probe (15) which can be guided from its proximal end so that the distal tip (16) thereof is positioned into contact or close proximity to the stenotic or occlusive material to be ablated. An imaging system (20) allows for the direct observation of the stenosis or occlusion so that contact with or close proximity of the probe's distal tip to the stenotic or occlusive material is maintained to ensure effective ablation with little or no remnant thereof after the procedure.

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ULTRASONIC ABLATION OF STENOSES AND OCCLUSIONS WITH IMAGING GUIDANCE

Background of the Invention

This invention generally relates to the treatment of a stenotic or occluded region of a body lumen by ultrasonic ablation and particularly to a catheter for the ablation of blood vessels such as coronary and peripheral arteries.

There are presently several treatment modalities for stenotic or occluded arteries, including balloon and laser angioplasty, atherectomy, by-pass surgery and the like. While each of the above-mentioned treatments has its advantages, each also has its disadvantages. For example, balloon angioplasty has been found to be highly successful in a wide variety of stenoses but there are some stenoses which are too tough to be effectively

dilated by an inflatable balloon. Similarly, directional atherectomy has been found to be very successful in soft to medium hardness plaque but is found to be relatively ineffective in very hard, highly calcified plaques.

Laser treatments, hot or cold, and other hot-tipped or heated balloon catheters have also been found to be successful in some stenoses, but the restenosis rate has been disappointingly high. Additionally, the high temperatures frequently developed by some of these devices can damage the arterial lining and can also cause considerable pain. By-pass surgery has likewise been found to be successful but such surgery involves a traumatic intrusion into the patient's body and can debilitate the patient for an extended period, even if successful.

Ultrasonic treatments of the stenotic buildup in peripheral arteries have also been suggested, see for example U.S. Patent No. 4,870,953 to (Don Michael *et al.*). While the ultrasonic treatment described by Don Michael *et al.* has been found to be effective in the ablation of plaque, particularly highly calcified plaque, the procedure leaves a substantial amount of residual blockage. What has been needed and has been heretofore unavailable is an ultrasonic treatment system which can be used to more completely ablate occluded and stenotic regions of blood vessels and other body lumens. The present invention satisfies these and other needs.

Summary of the Invention

This invention is directed to a system and method for the treatment of stenotic and occluded regions of body lumens such as arteries with a real time imaging means to guide an ultrasonic ablation means which is particularly suitable for peripheral and coronary arteries.

The ultrasonic treatment system of the present invention includes an elongated intravascular catheter with an ultrasonic probe extending from the distal end of the catheter which is adapted to be brought in to contact with the stenosis (*e.g.* atherosclerotic plaque) or the occlusive material (*e.g.* thrombus) within a patient's body lumen. The distal tip of the ultrasonic probe is adapted to emit ultrasonic energy at a frequency and amplitude sufficient to ablate plaque, thrombus and other blockage within a body lumen. The ablation system of the invention includes a means on the distal end of the catheter which provides a real time image of the inside of the body lumen which shows the stenosis or occlusive material at the distal end of the catheter to facilitate the accurate placement of the distal tip of the ultrasonic probe by the operator to ensure proper placement of the probe tip with respect to the stenosis or occlusive material for effective ablation. Means are preferably provided to guide the distal tip of the ultrasonic probe

from the proximal end of the catheter under direct observation by the imaging means.

The catheter assembly for the ultrasonic ablation of stenotic or occlusive material within a patient's body lumen in accordance with this invention comprises an elongated catheter shaft with at least one inner lumen extending therein; an elongated probe member having proximal and distal ends which is slidably disposed within the inner lumen of the catheter shaft and which has means at the distal end thereof for emitting ultrasonic energy at a frequency and amplitude sufficient to ablate stenotic or intraluminal blockage such as occlusive material; and means on a distal part of the catheter assembly for the real time imaging of the internal profile of the patient's body lumen; and means operable from the proximal end of the elongated probe for adjusting the position of the distal end of the elongated probe member within the body lumen so as to bring the ultrasonic energy emitter at the distal end of the catheter shaft into close proximity to, preferably in contact with, stenotic or occlusive material within the body lumen so as to more effectively ablate this material.

In a presently preferred embodiment of the invention the imaging system is an ultrasonic imaging system on the distal end of the catheter which emits ultrasonic energy to the stenotic or occlusive material within

the body lumen about the distal end of the catheter, senses ultrasonic energy reflected from the stenotic or occlusive material and develops an image of the body lumen from the sensed reflected ultrasonic energy. The ultrasonic image can be of a transverse cross-sectional profile or a longitudinal cross-sectional profile depending upon the orientation of the ultrasonic energy emission and reception. A plurality of ultrasonic transducers for emission and reception may be disposed in a fixed position in the distal end of the catheter shaft. Alternatively, an ultrasonic transducer may be mounted for rotation, *e.g.* on a rotatable shaft, to emit ultrasonic energy. In yet another embodiment an ultrasonic energy reflector may be mounted for ratation on a rotatable shaft with a ultrasonic transducer fixed adjacent to the rotating reflection. Other ultrasonic imaging as well as nonultrasonic imaging systems may be employed.

A variety of means to position the ultrasonic ablation probe tip may be provided. For example, the distal end of the probe can be curved or bent so that rotation of the probe from the proximal end thereof will move the probe's distal tip transversely in the body lumen. Other means to position the distal probe tip adjacent to or in contact with stenosis or occlusive material include systems which are used to deflect the distal tip of guidewires. Such systems are described in U.S. Patent 4,940,062; U.S.

Patent 4,886,067 and U.S. Patent 4,815,478 which are incorporated into this application by reference.

By providing a means to move the distal tip of the ultrasonic probe within the body lumen and an imaging means which provides real time imaging of the body lumen, the distal probe tip can be guided by the physician while observing the image produced by the imaging system to ensure effective placement of the probe tip with respect to the stenotic or occlusive material to provide more effective ablation. Moreover, the system allows the physician to observe the amount of residual stenosis or occlusive which exists after treatment so that further ablation can be performed, if needed, before the catheter is removed from the body lumen.

These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

Brief Description of the Drawings

Fig. 1 is an elevational view, partially in cross-section, of a catheter embodying features of the present invention.

Fig. 2 is a transverse cross-sectional view of the embodiment shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is a transverse cross-sectional view of the embodiment shown in Fig. 1 taken along the lines 3-3.

Fig. 4 is a longitudinal cross sectional view of an alternative embodiment of the invention.

Fig. 5 is a transverse cross-sectional view of the embodiment shown in Fig. 4 taken along the lines 5-5.

Fig. 6 is a from elevational view of the embodiment shown in Fig. 4 taken.

Fig. 7 is a partial longitudinal cross-sectional view of yet another embodiment of the present invention.

Fig. 8 is a transverse cross-sectional view of the embodiment shown in Fig. 7 taken along the lines 8-8.

Fig. 9 is a partial longitudinal cross-sectional view of yet another embodiment of the present invention.

Fig. 10 is a transverse cross-sectional view of the embodiment shown in Fig. 9 taken along the lines 10-10.

Fig. 11 is a partial longitudinal cross-sectional view of yet another embodiment of the present invention.

Fig. 12 is a transverse cross-sectional view of the embodiment shown in Fig. 11 taken along the lines 11-11.

Detailed Description of the Invention

Reference is made to Figs. 1-3 which schematically illustrate a presently preferred embodiment of the invention. As shown, the catheter 10 generally includes a catheter shaft 11 which has inner lumens 12 and 13 extending therein, an adaptor assembly 14 on the proximal end of the catheter shaft, an elongated ultrasonic probe 15 which has an enlarged, relatively blunt distal tip 16 for emitting ultrasonic energy to ablate stenotic or occlusive material, and an ultrasonic transducer assembly 17 for imaging the walls of the blood vessel.

The inner lumen 12 of the catheter shaft 11 is adapted to slidably receive the shaft 18 of the ultrasonic probe 15 and may have a diameter which is smaller than the distal tip 16. As shown the distal portion of the shaft 18 is curved or bent when extended beyond the distal end of the catheter shaft 11. Longitudinal movement of the probe 15 in and out of the inner lumen 12 in the shaft 11 will change the distance away from a longitudinal axis 19 of the probe 15 and provide another parameter to vary the transverse position of the tip 16 within the patient's artery. A source (not shown) of ultrasonic energy is connected to the proximal end of the probe 15 and when activated the ultrasonic energy travels through the shaft 18 to the blunt distal tip 16. Alternatively, an ultrasonic transducer may form part or all of the distal tip. Rotation and longitudinal movement of the probe shaft 18 allows the operator to precisely position the distal tip 16 in contact with or close proximity to the stenotic or occlusive material to provide more effective ablation thereof. Direct contact of ultrasonic probe tip 16 with the stenotic or occlusive material greatly enhances the ablation capability of the tip.

The ultrasonic energy is transmitted through probe shaft 18 to the distal tip 16 should be within a frequency range of about 17 KHz to about 100 KHz so that tip 16 vibrates with sufficient frequency and amplitude to

ablate the stenosis or occlusive material. A suitable ultrasonic energy source is disclosed in U.S. Patent No. 4,870,953 to Don Michael *et al.* If an ultrasonic transducer forms all or part of the distal tip 16, the frequency range of the ultrasonic energy should be about 100 KHz to about 1 MHz as described in copending application Serial No. 625,919, filed December 10, 1990 entitled MINIATURE ULTRASONIC TRANSDUCER FOR PLAQUE ABLATION AND CLOT DISSOLUTION, which is incorporated herein by reference.

To effect transverse movement of the distal tip of the probe, the distal section of the probe shaft 18 may be shaped, *e.g.* curved, before inserting catheter 10 into the patient by manually curving or bending the distal section. The distal tip 16 may then be positioned within the patient's arterial passageway by rotating the probe and/or longitudinally moving the distal section in and out of the port 19 in the distal end of the catheter shaft 11. Other means can be provided to shape the distal section after the catheter has been inserted into the patient. For example, the distal portion may be structured as the guidewires described in U.S. Patent 4,940,062; U.S. Patent 4,886,067 and U.S. Patent 4,815,478 which have been incorporated into this application. In these embodiments the distal tips are deflected by actuating the probe in the prescribed manner. Other means includes using a probe tip formed of a shape memory alloy which changes

shape upon a phase transformation. An exemplary type of shape memory alloy material which can be used is a Niti alloy such as Nitinol. At temperatures at or above body temperature the alloy is in the austenite phase and the shape of the metal in this phase is the shape "remembered". At temperatures below body temperature, the material is in a martensite phase and, when it is plastically deformed, it retains its shape. When the temperature of the metal is increased above a certain level above the temperature at which the martensite is stable, at or above body temperature, the metal transforms from the martensite phase to the austenite phase and the metal returns to its "remembered" shape.

The imaging system 17, which is adapted to facilitate directing the distal tip 16, includes a shaft 20 which is rotatably disposed within the inner lumen 13 of the catheter shaft 11 and is provided with an imaging transducer 21 on the distal end thereof which preferably both emits and receives ultrasonic signals. Separate transducers can be employed for both functions. Means (not shown) are provided on the proximal end of the shaft 20 to rotate the shaft and the imaging transducer 21 on the distal end of the shaft. Electrical conductors (not shown) are provided on or in the shaft 18 which are connected to the terminals of the imaging transducer 21. Slidable contacts 22 and 23, which may be spring biased contacts, brush contacts or other equivalent slidable contacts. are secured to the proximal

portion of the shaft 20 which extends out of the central arm 24 of the adapter assembly 14 and are adapted to electrically engage the conductors provided with the shaft 20 to provide electrical power to the imaging transducer 21 and to receive the electrical signals which are generated by the imaging transducer upon receiving the ultrasonic echoes reflected from the stenotic or occlusive material on the arterial wall. Alternatively, an inductive coupling system may be employed. Conductors 24 and 25 electrically connect the sliding contacts 22 and 23 to the controller 26 which also includes a video screen which is used to display the interior of the body lumen. Rotation of the shaft 20 about its longitudinal axis rotates the imaging transducer 21 which emits ultrasonic energy to a peripheral region on the inner surface of the arterial passageway and receives ultrasonic echoes therefrom which are converted to electrical signals and which when directed to the controller unit 26 generate a transverse cross-sectional image of the interior of the blood vessel on the video display screen 27. In the embodiment shown in Fig. 1, imaging transducer 21 is rotated around its longitudinal axis which is in line and parallel to the longitudinal axis 19 of drive shaft 20 to image a region of the blood vessel wall since transducer 21 is a two dimensional transducer which can only generate an image within a plane radiating from the axis of rotation of transducer.

Imaging transducer 21 preferably includes means to generate and emit ultrasonic energy toward the stenosis or occlusive material on the interior surface of the arterial passageway, means to sense the ultrasonic echo from the stenotic or occlusive material and means to generate electrical signals representative of the magnitude and frequency of the ultrasonic energy reflected from stenotic or occlusive material or the difference between the ultrasonic energy emitted and the reflected ultrasonic energy received. The imaging transducer 21 may be a conventional ultrasonic transducer formed of suitable piezoelectric material such as barium titanate or cinnabar.

A relatively short guidewire receiving inner lumen 30 is provided in the distal portion of the catheter shaft 11 which allows for the rapid exchange of the catheter of the invention over guidewire 31 with other diagnostic or therapeutic catheters, *e.g.* balloon angioplasty or atherectomy catheters without the need for exchange wires or extension wires.

Adaptor assembly 14 is provided with side arms 32 and 33 which are in fluid communication with the inner lumens 12 and 13 respectively. Typically, contrast fluid will be directed through side arm 32 into the inner lumen 12 to fluoroscopically observe the procedure. Irrigation fluid may be directed through the side arm 33 into the inner lumen 13 to keep debris

away from the imaging transducer 21 and the observation field. Fluids containing therapeutic agents may also be directed to the distal end of the catheter shaft through these inner lumens.

Preferably, the window portion 34 of the elongated catheter shaft 11 located about the imaging transducer 21 at the distal end of catheter 10 is relatively transparent to the ultrasonic energy so that ultrasonic energy from imaging transducer can be transmitted and received with minimal interference.

The adaptors and ultrasonic probes described in U.S. Patent No. 4,870,953 to Don Michaels *et al.*, which is incorporated by reference herein, are suitable for use with the present invention. Also, U.S. Patent Nos. 4,794,931, 5,000,185 and 5,026,586 to Yock disclose adaptor structures, ultrasonic transducers and imaging techniques which may be used in the present invention, which are incorporated herein by reference.

The catheterization process for coronary arteries includes percutaneously inserting a guiding catheter into the patient's femoral or brachial arteries by a Seldinger technique and seating the distal tip of the guiding catheter within the ostium of the desired coronary artery. The guiding catheter is relatively stiff and the distal end of the catheter is

usually preformed in a specific shape which facilitates seating the distal end within the ostium. For peripheral arteries a guiding catheter is usually unnecessary.

The catheter 10 of the invention is preferably advanced over a guidewire 31 until the distal tip of catheter 10 is positioned within the stenosis or within the occlusion for ablation of the material thereof. If the anatomy of the blood vessels near to the stenosis is tortuous a guidewire may be used to help position the distal tip of catheter 10. The guidewire 31 as shown has an elongated core member 35 and a coiled wire spring tip which permits the guidewire to be directed through a blood vessel without traumatic engagement with the blood vessel walls.

In an alternative embodiment of the invention, the probe lumen 12 could serve as the guidewire lumen. That is, the guidewire would be positioned, if necessary, and then catheter 10 would be advanced over the guidewire to the stenosis with the guidewire being small enough to be readily moveable through inner lumen 12. Once catheter 10 is in position close to the stenosis, the guidewire would be withdrawn through probe lumen 12 to allow ultrasonic probe 14 to be introduced into the stenotic region of the blood vessel lumen through the lumen 12.

Once ultrasonic probe 14 is properly in place within the stenosis or occlusion, the process of ablation may be initiated. Ultrasonic energy emitted from probe tip 16 ablates the plaque of the stenosis or other material. The operator torques the proximal end of the probe shaft 18 and/or moves the probe longitudinally so that the distal blunt tip 16 is placed in direct contact with the plaque or other occlusive material on the arterial wall.

The imaging system 17 allows the physician to monitor the positioning of the probe tip 16 to ensure that the tip is in direct contact with the stenotic or occlusive material. Thus, the transducer emits ultrasonic energy, receives the reflected ultrasonic energy and generates a signal representing the reflected energy which may be used to form an image of the region of the stenosis and the position of ultrasonic probe tip 16. The portion of the blood vessel wall which is imaged is limited by the size of transparent portion 29 and ultrasonic transducer.

Figs. 4-6 illustrate another embodiment of the invention wherein a scanning array of stationary transducers, typically about 30 to about 70 are positioned in an annular configuration about the interior of the distal end of the catheter and adapted to emit ultrasonic energy radially outwardly and to receive the reflected ultrasonic energy so that a signal can be developed

which enables an image of the interior of a blood vessel to be formed. Inner lumen 41 is adapted to slidably receive a probe 42 and is provided with a ramp 43 which directs the distal tip 44 of the probe out the port 45 in the wall of the catheter shaft 46 when the probe 42 is advanced distally within the inner lumen. With the probe tip 44 in the region of irradiation, the probe tip 44 is directly visualized with respect to the inner surface of the body lumen which allows a more accurate placement of the probe tip. A positioning balloon 47 (shown in phantom) may be formed in the portion of the outer sheath 48 on the side of the catheter shaft 46 opposite the exit port 45. Inflation fluid passed through inner lumen 49 is directed to the interior of the balloon 47 to inflate the balloon 47. The inflation and deflation of the balloon 47 changes the position of the distal end of the balloon within the interior of the blood vessel allowing another parameter of positional control of the distal tip 44 of the probe. The distal end of the probe 42 may be curved to facilitate the advancement out the port 45. The guidewire lumen 50 slidable receives the guidewire 51 which allows the advancement of the catheter 52 over the guidewire to the desired location within the patient's blood vessel. The guidewire receiving lumen 50 may extend to the proximal end of the catheter 52 in a conventional over-the-wire construction as shown or the lumen may be adapted to allow for the rapid exchange of the catheter and thus be relatively short and be disposed

within the distal portion of the catheter shaft. In the latter instance the lumen 52 would have to be offset from the inflation lumen 49.

Another presently preferred embodiment of the invention is illustrated in Figs. 7 and 8. In this embodiment, catheter 60 has an ultrasonic transducer 61 to transmit ultrasonic energy to and to receive reflected ultrasonic energy from a rotating angled reflector 62. The rotating angled mirror 62 is secured to the distal end of the shaft 63 which extends through the inner lumen 64 as discussed previously with the other embodiments and the transducer 61 is secured to the leading edge of the reflector 62. Rotation of the shaft 63 rotates both the transducer and the angled reflector 62. Alternatively, as shown in phantom, the transducer 61 may be fixed to the catheter adjacent to but unconnected to the reflector 62. The distal section of the catheter 60 is provided with a short inner lumen 65 which is adapted to slidably receive a guidewire 66. The probe 67 is disposed within the inner lumen 68 and is essentially the same as in the previous embodiments. This embodiment operates is a fashion similar to the previously discussed embodiments.

Figs. 9 and 10 depict yet another presently preferred embodiment of the invention wherein catheter 70 is provided with a probe 71 with a deflectable distal tip 72. The probe is formed of NiTi alloy which has a

final austenite temperature above body temperature and has a curved "memory" but is inserted into the catheter in the martensite in a straight condition. The probe tip 72 is resistance heated to a temperature above the final austenite transformation temperature which causes the probe to return to its "remembered" curved shape. The distal section of the catheter 70 is provided with a short inner lumen 73 which is adapted to slidably receive a guidewire 74. The probe 71 is disposed within inner lumen 75 and is essentially the same as in the previous embodiments. An array of piezoelectric transducers 76 are provided on the distal tip of the catheter 70 and are oriented distally so as to image the body lumen distal to the distal tip of the catheter.

Figs. 11 and 12 illustrate yet another embodiment of the invention wherein a plurality of ultrasonic transducers 80 are positioned in a linear configuration of the catheter and adapted to emit ultrasonic energy radially outwardly along a length of the catheter and to receive the reflected ultrasonic energy from the arterial wall so that a signal can be developed which enables an longitudinal cross sectional image of the interior of a blood vessel to be generated. Inner lumen 81 within catheter 82 is adapted to slidably receive a probe 83 and is provided with a ramp 84 which directs the distal tip 85 of the probe out the port 86 in the wall of the catheter shaft 87 when the probe is advanced distally within the inner lumen. With

the probe tip 85 in the region of irradiation by the transducer 80, a more accurate image is formed of the probe tip with respect to the inner surface of the blood vessel which allows a more accurate placement of the probe tip, as in the case of the embodiment of Figs. 4-6. The distal end of the probe 83 may be curved to facilitate the advancement out the port 86. The guidewire lumen 88 slidably receives the guidewire 89 which allows the advancement of the catheter 82 over the guidewire to the desired location within the patient's blood vessel. The guidewire receiving lumen 88 may extend to the proximal end of the catheter 82 in a conventional over-the-wire construction as shown or the lumen may be adapted to allow for the rapid exchange of the catheter and thus be relatively short and be disposed within the distal portion of the catheter shaft as shown in Figs. 1, 7 and 10.

The ultrasonic energy for the blunt, relatively enlarged distal tip of the probe may be supplied from the proximal end of the probe or an ultrasonic transducer may be provided on the distal end of the probe. A suitable ultrasound energy source which may be provided on the distal end of the probe is described in copending application Serial No. 625,919 which has been incorporated in its entirety herein by reference.

The principal application for ultrasonic ablation of stenoses and other occlusions has heretofore been with completely blocked peripheral arteries.

During ultrasonic ablation with the catheter of the invention, the ultrasonic imaging techniques thereof can transmit an accurate image of a cross sectional view of the blockage and the progress of ablation so that the distal tip of the probe can be guided to and maintained in contact with or close proximity to the blockage to effectively remove it. In this manner essentially the entire blockage can be ablated with little or no remnant which can accelerate the reformation of stenosis.

The catheter of the invention has been described herein as having an ultrasonic probewhich is slidably disposed within an inner lumen within the catheter shaft in order to engage the distal probe tip with the stenosis or occlusive material by the longitudinal movement of the probe within the inner lumen. Alternatively, a curved distal probe tip may be secured to the distal end of the catheter and the entire catheter may be rotated and/or moved longitudinally in order to engage the stenosis or occlusive material with the probe tip to effectively ablate such material.

Various materials and construction techniques for the catheter of the invention may be conventional and well known to those of ordinary skill in the art according to the foregoing description. Moreover, it will be readily apparent to those skilled in the art that various modifications and additions can be made in the ultrasonic ablation catheter and the method of using the

catheter of the present invention without departing from the scope of the invention. For example, the unitary construction illustrated is only representative and in practice the distal tip portions may be separate elements which are secured onto catheter shaft. To the extent that materials and construction techniques are not specifically disclosed herein conventional materials and construction techniques may be employed. While the invention has been described herein in terms of intravascular uses, those skilled in the art will recognize that the catheter assembly may be employed in other body lumens of the patient such as in the gall bladder to ablate gall stones or in a patient's urethra to treat benign prostatic hyperplasia. The catheter assembly may also be utilized in artificial lumens formed in a patient's body. Other uses and modifications may be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A catheter assembly for ultrasonic ablation of stenotic or occlusive material within a patient's body lumen comprising:

(a) an elongated catheter shaft having proximal and distal ends;

(b) an elongated ultrasonic probe member having a distal tip with means for emitting ultrasonic energy at a frequency and amplitude sufficient for ablation of stenotic or occlusive material within the body lumen;

(c) means for positioning the distal tip of the elongated ultrasonic probe member within the body lumen in close proximity or in contact with the stenotic or occlusive material within the body lumen to be ablated; and

(d) means located at the distal end of the catheter shaft for imaging the internal profile of the patient's body lumen to allow an operator to guide the distal tip of the ultrasonic probe under direct observation by the imaging means.

2. The catheter assembly of claim 1 wherein the catheter shaft is provided with an inner lumen and the ultrasonic probe member is slidably disposed with the inner lumen.

3. The catheter assembly of claim 1 wherein the means for positioning the distal tip of the ultrasonic probe member is operably from the proximal end of the elongated catheter shaft.

4. The catheter assembly of claim 1 wherein the inner lumen is adapted to direct fluid out an opening in the distal end of the catheter shaft.

5. The catheter assembly of claim 1 wherein the ultrasonic probe member has a core element with a longitudinal axis with the distal tip of the core element at an angle with respect thereto so that rotation of the core member within the inner lumen within the elongated catheter shaft about the longitudinal axis will adjust the transverse position of the distal tip to facilitate contact with material within the body lumen to be ablated.

6. The catheter assembly of claim 1 wherein said means for positioning the distal tip includes an inflatable positioning balloon for positioning the distal tip of the catheter assembly toward one side of the patient's body lumen.

7. The catheter assembly of claim 1 wherein said means for positioning the distal tip includes a deflection wire attached proximate to the distal end of said elongated core member.

8. The catheter assembly of claim 1 wherein said core member is a solid wire.

9. The catheter assembly of claim 6 wherein said energy emitting tip is enlarged and blunt.

10. The catheter assembly of claim 1 wherein said core element is a hollow wire having an energy emitting tip at the distal end.

11. The catheter assembly of claim 1 wherein said means for emitting ultrasonic energy includes a piezoelectric crystal capable of oscillating at an ultrasonic frequency which ablates stenosis or occlusive material.

12. The catheter assembly of claim 1 wherein said means for emitting ultrasonic energy includes means for receiving ultrasonic energy transmitted along the length of said elongated core element.

13. The catheter assembly of claim 1 wherein the means to image the internal profile of the body lumen has a plurality of ultrasonic transducers.

14. The catheter assembly of claim 13 wherein the transducers are disposed radially about the distal end of the catheter to provide an image of a transverse cross-sectional view of the body lumen.

15. The catheter assembly of claim 13 wherein the transducers are disposed longitudinally along the distal end of the catheter to provide a longitudinal cross-sectional view of the body lumen.

16. A system for ablating stenosis or ablative material within a patient's body lumen comprising:

(a) an elongated catheter shaft having proximal and distal ends and an inner lumen extending therein;

(b) means at the distal end of the elongated catheter body for emitting ultrasonic energy to the body lumen proximal to the distal end;

(c) means at the distal end of the elongated catheter body to sense ultrasonic energy reflected from the body lumen;

(d) means to develop an image of the body lumen from the sensed reflected ultrasonic energy;

(e) an elongated probe disposed within the inner lumen of the elongated catheter shaft with means on the distal tip of the probe to emit ultrasonic energy sufficient to ablate stenotic or occlusive materials; and

(f) means operable from the proximal end of the catheter to adjust the location of the distal tip of the probe within the body lumen so as to ablate stenotic or occlusive material located by the imaging means with ultrasonic energy from the ultrasonic energy emitting means on the distal tip of the elongated probe.

17. A method for ablating stenotic or occlusive material lining a patient's body lumen, comprising:

a) providing an intraluminal catheter including,

an elongated catheter shaft having proximal and distal ends;

an elongated ultrasonic probe member having a distal tip extending from the distal tip of the catheter which has means at its distal tip for emitting ultrasonic energy at a frequency and amplitude sufficient for

ablation of stenotic or occlusive material within the body lumen;

means, operable from the proximal end of said elongate catheter shaft, for positioning the distal tip of the ultrasonic probe member within the body lumen in close proximity or in contact with the stenotic or occlusive material within the body lumen to be ablated; and

means located at the distal end of the catheter shaft for imaging the internal profile of the patient's body lumen to allow an operator to guide the distal tip of the ultrasonic probe under direct observation by the imaging means;

b) advancing the catheter within the patient's body lumen until the distal end of the catheter is disposed at a desired location within the body lumen;

c) positioning the distal tip of the ultrasonic probe in contact or close proximity to the stenotic or occlusive material to ablated while directly observing the movement of the probe's distal tip with respect to the stenotic or occlusive material to be ablated by the imaging means on the distal end of the catheter; and

d) emitting ultrasonic energy from the distal tip of the ultrasonic probe to ablate the stenosis or occlusive material within the patient's body lumen.

AMENDED CLAIMS

[received by the International Bureau on 14 December 1994 (14.12.94); original claim 1 amended; remaining claims unchanged (1 page)]

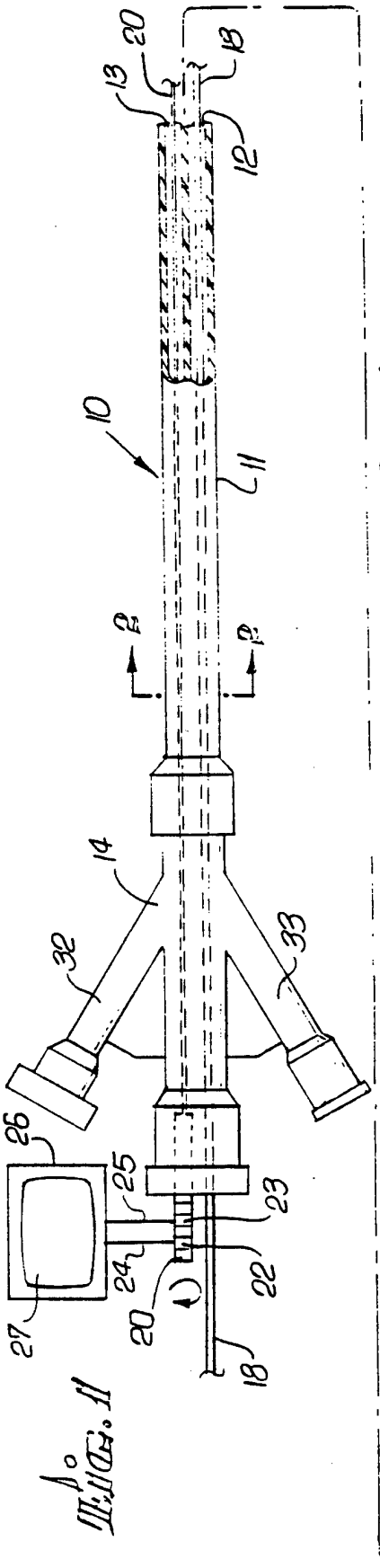
1. A catheter assembly for ultrasonic ablation of stenotic or occlusive material within a patient's body lumen comprising:

(a) an elongated catheter shaft having proximal and distal ends;

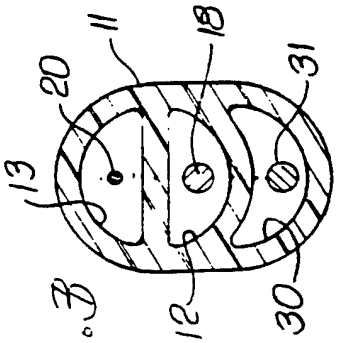
(b) an elongated ultrasonic probe member having a distal tip with means for emitting ultrasonic energy at a frequency and amplitude sufficient for ablation of stenotic or occlusive material within the body lumen;

(c) means for positioning the distal tip of the elongated ultrasonic probe member within the body lumen in close proximity or in contact with the stenotic or occlusive material within the body lumen to be ablated; and

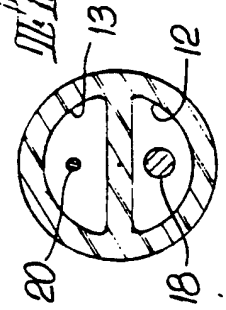
(d) ultrasonic means located at the distal end of the catheter shaft for imaging the internal profile of the patient's body lumen to allow an operator to guide the distal tip of the ultrasonic probe under direct observation by the ultrasonic imaging means.



Фиг. 1



Фиг. 3



Фиг. 2

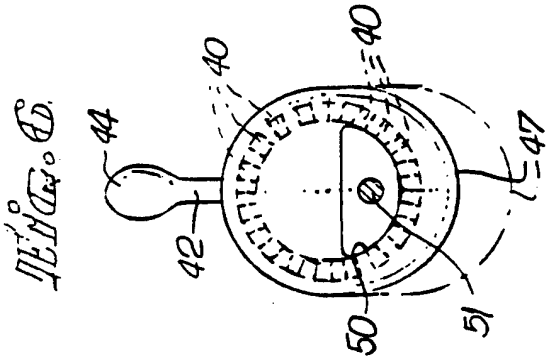


FIG. 6.

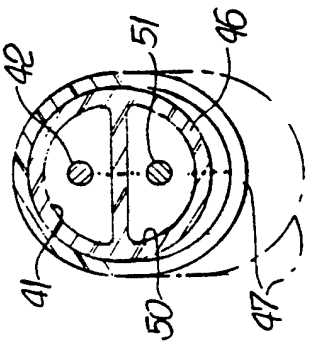


FIG. 5.

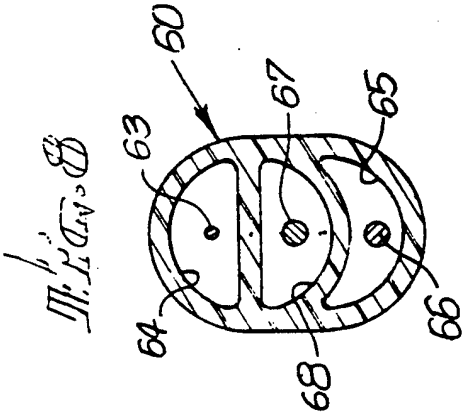


FIG. 8.

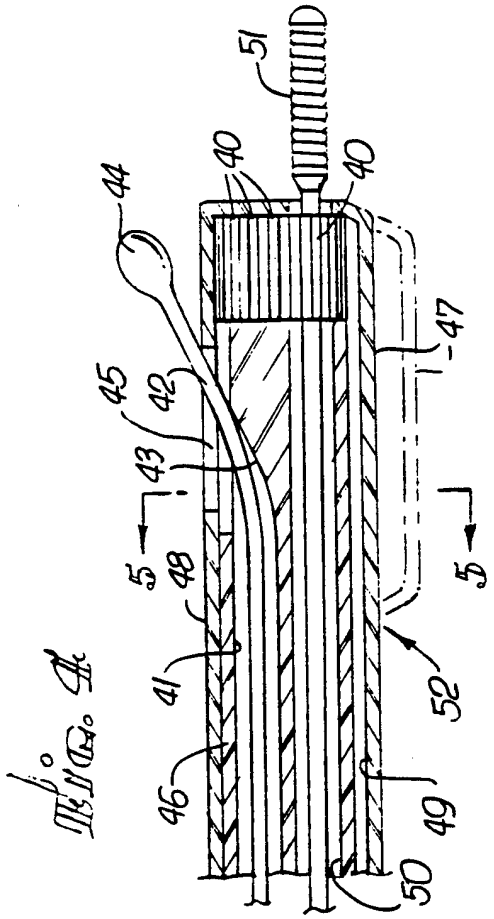


FIG. 4.

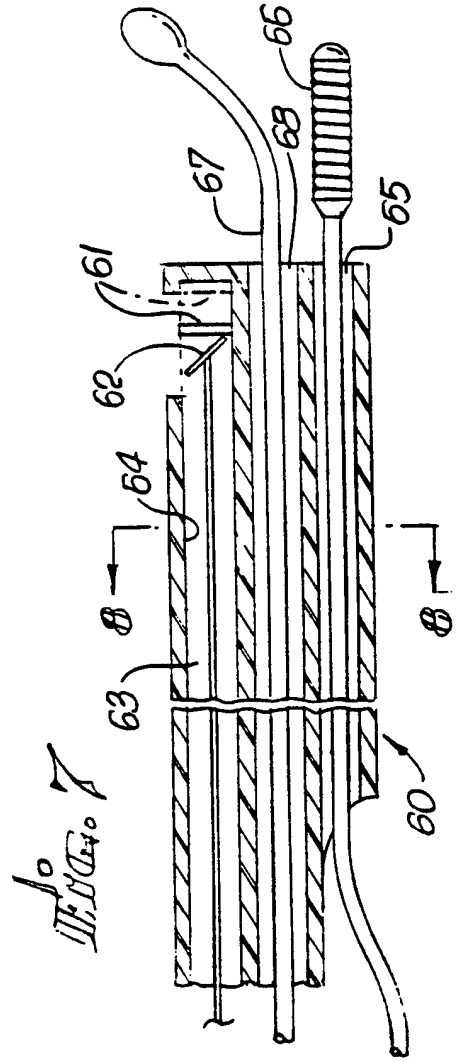


FIG. 7.

FIG. 10

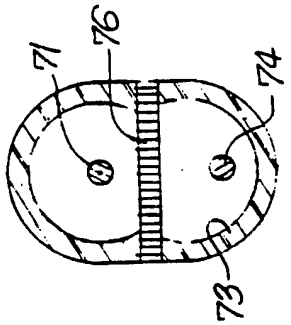


FIG. 12

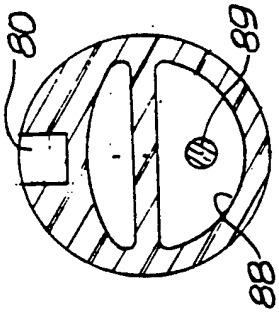


FIG. 9

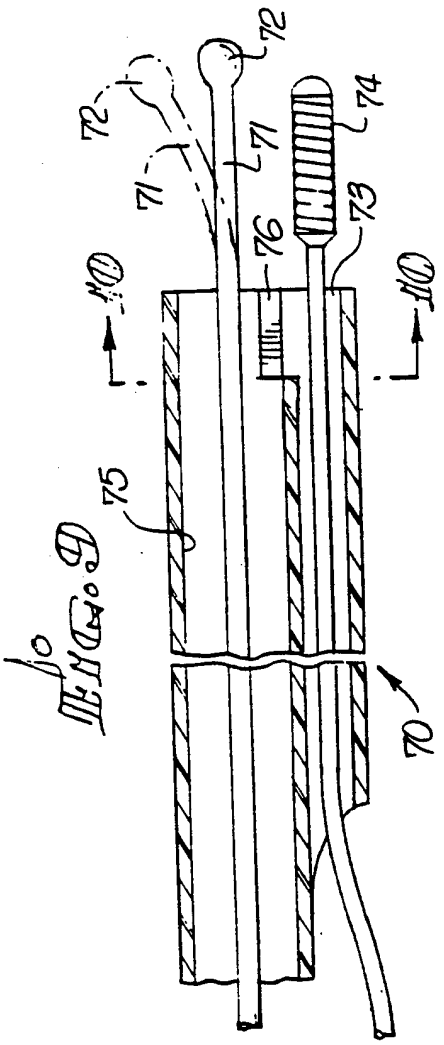
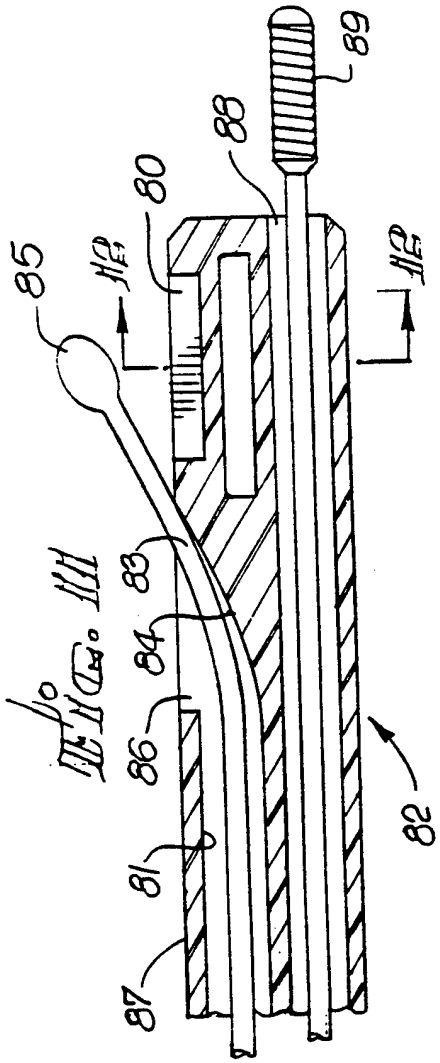


FIG. 11



INTERNATIONAL SEARCH REPORT

Inter ›nal Application No
PCT/US 94/00484

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO,A,92 11815 (BAXTER) 23 July 1992 see page 13, line 14 - page 15, line 24 see page 20, line 10 - line 14 see page 21, line 5 - line 16 see page 33, line 14 - page 34, line 14; figures 1,5,16	1-5,8,9 6,10-16
Y	US,A,4 924 863 (STERZER) 15 May 1990 see column 5, line 44 - line 68; figures 2A,B	6
Y	EP,A,0 443 256 (URCAN MEDICAL) 28 August 1991 see abstract; figure 2	10

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
15 September 1994	14. 10. 94

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Moers, R

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	DE,A,41 15 742 (ANGIOMED) 19 November 1992 see column 5, line 5 - line 53; figure 1	13-16
A	EP,A,0 347 098 (SHIBER) 20 December 1989 see column 5, line 44 - column 6, line 13; figure 2	12
A	US,A,5 242 386 (HOLZER) 7 September 1993 see column 2, line 63 - column 3, line 7; figures 1,2	15
A	WO,A,89 07909 (LABORATORY EQUIPMENT CORP.) 8 September 1989 see abstract; figure 5	1,13,16

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Information on patent family members

Int. ional Application No
PCT/US 94/00484

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